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Section E – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

Name:	Cameron Mahon Director of R & D
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Telephone:	(905) 829-5300
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E-mail:	research@XLTEK.com
Common Names:	LED Visual Stimulator Goggles
Classification Name:	21 CFR § 882.1890, Stimulator Photic Evoked Response, 84 GWE, Class II
Predicate Devices:	XLTEK Real Patient EP 8 [510(k) # K010092]
Description:	LED Visual Stimulator Goggles are goggles that are used to stimulate the eyes to record an electrical response from the brain. LEDs inside the goggles flash light at the eye. An electrical signal from the brain in response to this stimulus is recorded by an evoked potential stimulator headbox.
Substantial Equivalence:	When used as an accessory with the Stim 1000 A/V [510(k) #K972157], the LED Visual Stimulator Goggles are substantially equivalent in terms of safety and effectiveness to the Grass-Telefactor LED Goggles manufactured by Astro-Med, Inc. Grass-Telefactor LED Goggles were designed prior to the 1976 Medical Device Amendment to the U.S. Food and Drug law, so were

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"grandfathered" into being listed as "medical devices" in the U.S. The Grass-Telefactor LED Goggles that we are claiming substantial equivalence to have been listed in this way and thus do not have an FDA 510(k) or PMA listing.

Indications for Use:

The LED Visual Stimulator Goggles are intended to flash visible light into a patient's eyes. The LED Visual Stimulator Goggles are designed to be used in hospital and clinical settings by trained medical personnel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Mr. Cameron Mahon
Vice President, Regulatory Affairs
Excel Tech, Ltd.
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

Re: K011794
Trade/Device Name: LED Visual Stimulator Goggles
Regulation Number: 882.1890
Regulatory Class: II
Product Code: GWE
Dated: August 7, 2001
Received: August 14, 2001

Dear Ms. Markez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walk, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D – Statement of Indications for Use

510(k) Number (if known): K011794

Device Name: LED Visual Stimulator Goggles

Indications for Use: The LED Visual Stimulator Goggles are intended to flash visible light into a patient's eyes. The LED Visual Stimulator Goggles are designed to be used in hospital and clinical settings by trained medical personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011794